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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/101,723 08/13/98 DARVISH

N 20066-05

EXAMINER

QM12/0812

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LAUREN C PAPER NUMBER

6

3737

DATE MAILED:

08/12/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 8/27/98
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1 - 58 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) 27, 46, 54 AND 57 is/are allowed.
- Claim(s) 1 - 26, 28-45, 47-53, 55, 56, AND 58 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on 8/27/98 is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d):
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 3737

## **DETAILED ACTION**

### ***Preliminary Amendment***

1. Acknowledgment is made of applicant's amendment which was received by the Office on July 8, 1998. This document has been made of record in the file as Paper No.1½.

### ***Information Disclosure Statement***

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on November 2, 1998. This document has been made of record in the file as Paper No.2.

### ***Drawings***

3. This application has been filed with informal drawings which are acceptable for examination purposes only. See attached PTO-948 with Draftsperson's comments.
4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following features must be shown or the feature(s) canceled from the claim(s).
  - An implantable light source, a plurality of light sources, and a waveguide - Claims 52 and 55, and

Art Unit: 3737

- A means for irradiating and means for repeating irradiating - Claim 53 and 56.

No new matter should be entered.

***Specification***

5. This application does **not contain an abstract** of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

6. The disclosure is objected to because of the following informalities:

-p.1, lines 13-14, the status of U.S Application Serial Number 08/595,365 should be updated to reflect that this is now U.S Patent Number 5,738,096.

-p.10, line 32, the word “of” should be “or”, and

-p.34, line 23, the term “DC filed” should be “DC field” .

Appropriate correction is required.

***Claim Objections***

7. Claims 11, 13-15, and 43-45 are objected to because of the following informalities:

- Claims 11 and 13-15, as amended, now recite the redundant and potentially confusing statement “according to any one of claim 1”. For clarity, the Examiner suggests omitting the words “any one of”.

Art Unit: 3737

- Likewise, Claims 43-45, as amended, now recite the repetitive statement "according to any one of claim 30". Again, the Examiner suggests omitting the words "any one of". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 52 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. No specific support could be found in the specification for providing a light source capable of generating light for "at least 1000 cardiac cycles, over a period of less than 5000 cycles".
10. Claims 53 and 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. No specific support could be found in the specification for providing a

Art Unit: 3737

“means for irradiating” capable of irradiating “at least 100 cardiac cycles, during a period of less than 1000 cycles”.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-26, 28-45, 47-51, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, line 3, there is no antecedent basis for the term “the desired change”.

It is unclear from the claim language what this change is suppose to be. To overcome this problem, the Examiner suggests substituting “a” for “the”. In addition, the phrase "such as" (line 4) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In regard to claims 3 and 4, the claims are indefinite in that no method steps are being recited. Only the structural features of the electrical field are described. To overcome this rejection, the Examiner suggests inserting in claim 3 the words “the step of applying” after the word “wherein” (line 1) and inserting the word “applying” after the word “comprises” (line 1). Likewise for claim 4, the Examiner suggests substituting the words “wherein the step of applying

Art Unit: 3737

the non-excitatory electric field comprises applying an electric field that has" for the words "wherein the non-excitatory electric field has".

In regard to claims 16-19, the phrase "such as" (line 4) renders each claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). To overcome this rejection, the Examiner suggests deleting the words "such as to be" in each claim.

In regard to claims 18 and 24-26, there is no antecedent basis for the term "the desired change" (line 3 of claim 18; line 2 of claim 24; line 5 of claims 25 and 26). It is unclear from the claim language what this change is suppose to be. To overcome this rejection, the Examiner suggests replacing this with the phrase "a desired change".

Regarding claim 23, the use of multiple "and/or" phrases (lines 4 and 5) renders the claim indefinite because it is unclear to the Examiner what the scope of the claim is (i.e. which embodiments are covered by the claim). See MPEP § 2173.05(h).

In regard to claim 30, the phrase "such as" (line 5) renders each claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). To overcome this rejection, the Examiner suggests deleting the words "such as".

In regard to claim 41, there is no antecedent basis for the term "the delay time". To overcome this rejection, the Examiner suggests replacing "the" with "a" in this phrase.

Art Unit: 3737

In regard to claim 47, the phrase "such as" (line 7) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). To overcome this rejection, the Examiner suggests deleting the words "such as to be".

***Allowable Subject Matter***

13. Claims 27, 46, 54, and 57 are allowed.

14. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 27 describes a method of treating an arrhythmic segment of a heart by increasing its excitation threshold using a "desensitizing electric field". None of the prior art references of record show or teach this capability.

Independent claim 46 describes a cardiac treatment apparatus having electrodes and circuitry for applying a "non-excitatory electric field" to the heart of a patient. The field generated is "unable" to generate a "propagating action potential". The claim is allowable since the prior art references of record (Kroll et al '876 and others) teach away from this ideal by using their electric fields to induce action potentials by capturing portions of a patient's heart chambers.

Independent claims 53 and 57 describe the inventive method and corresponding apparatus for applying a "non-excitatory electric field" to two portions of a heart chamber for either

Art Unit: 3737

increasing or decreasing a force of contraction. None of the prior art references of record show or teach this capability.

15. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

*Conclusion*

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Kroll et al '876 patent describes an implantable atrial defibrillator which also includes an electrical cardiac output forcing (ECOF) circuit which generates an electric field to counteract the effects of ventricular fibrillations. Unlike applicant's device, the electric field of Kroll et al causes the capture of a portion of the patient's ventricle which generates a "propagating action potential" to induce the heart to produce a minimum cardiac output at a fraction of its normal pumping power until the patient can receive an external defibrillation.

The Noren et al '966 patent also describes an implantable pacer/defibrillator which is capable of producing an electric dc field which appears to dampen the effects of abnormal cardiac

Art Unit: 3737

conduction (col.1, lines 51-55) without causing any depolarizations (col.2, lines 54-57).

Unfortunately, the filing date of Noren et al fails to pre-date the priority filing dates of applicant's 60/009,789 and 60/011,117 provisional applications.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on M-F from 8:30 AM to 5:00 PM. A voice mail message may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef, can be reached on (703) 308-3256. The current fax number for this Group is (703) 308-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Carl H. Layno

**Carl H. Layno**  
Patent Examiner

CHL

August 3, 1999